UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

HEALTHPOINT, LTD. and DPT LABORATORIES, LTD.,	)	
Plaintiffs,	)	**Civil Action No. SA-07-CA-0526-XR**
VS.	)	
ALLEN PHARMACEUTICAL, LLC, and PHARMA PAC, LLC	)	
Defendants.	)	

ORDER

On this date, the Court considered Defendants' Motion to Dismiss (docket no. 11). After considering the motion and applicable case law, the Court will DENY the motion.

I. Standard of Review

When considering a motion to dismiss for failure to state a claim under Rule 12(b)(6), the Court must generally base its decision only on the pleadings. FED. R. CIV. P. 12(b)(6); *McCartney v. First City Bank*, 970 F.2d 45, 47 (5th Cir. 1992). The Court must accept "all well-pleaded facts as true and . . . view them in the light most favorable to the plaintiff." *McCartney*, 970 F.2d at 47. "To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead enough facts to state a claim to relief that is plausible on its face." *In re Katrina Canal Breaches Litigation*, 495 F.3d 191, 205 (5th Cir. 2007). In other words, "factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if

doubtful in fact)." *Bell Atlantic Corporation v. Twombly*, 127 S.Ct. 1955, 1965 (2007).

II. Factual and Procedural Background

Plaintiffs Healthpoint, Ltd. and DPT Laboratories, Ltd. sued Defendants Allan Pharmaceutical, LLC, and Pharma Pac, LLC, alleging that they violated section 43 of the Lanham Act through false advertising and unfair competition.[1] Plaintiffs also assert claims against Defendants for common-law unfair competition and misappropriation.

In their Complaint, Plaintiffs explain that they manufacture Xenaderm, a wound-healing ointment, and market it for sale to doctors and healthcare providers. Plaintiffs allege that they have performed experiments and testing on XenaDerm to ensure its efficacy and have expended resources building brand awareness. Plaintiffs allege that Defendants manufacture AllanDerm and market it, directly and by implication, as a generic equivalent to and substitute for XenaDerm. Specifically, Plaintiffs allege that Defendants "falsely promote AllanDerm as a generic substitute for XenaDerm." Compl. ¶ 6. Plaintiffs allege that AllanDerm is not a generic equivalent to or substitute for XenaDerm. Compl. ¶ 18. Plaintiffs further allege that, before launching AllanDerm, Defendants did not perform any tests to determine if it was bioequivalent to or therapeutically equivalent to XenaDerm, nor did they spend the time and resources necessary to ensure that their product would be as pharmaceutically elegant and effective as XenaDerm. Compl. ¶ 12. Based on these facts, Plaintiffs assert four causes of action: (1) violation of Lanham Act § 43(a) (false advertising); (2) violation of Lanham Act § 43(a) (unfair competition); (3) common-law unfair competition; and (4) common-law misappropriation.

Defendants filed the instant 12(b)(6) motion to dismiss Plaintiffs' claims based on preclusion

[1] 15 U.S.C.A. § 1125.

by the FDA's primary jurisdiction to enforce the FDCA[2] and the failure to state a claim upon which relief can be granted. In support of their first basis for dismissal, Defendants assert that all of Plaintiffs' claims turn on the issue of whether AllanDerm is a generic equivalent to XenaDerm, and that question is within the exclusive jurisdiction of the FDA. Defendants contend that courts have held precluded claims based on marketing a product as an alternative, equivalent, or generic alternative, as well as a claim based on failing to sufficiently test a product according to FDA requirements. In support of their second basis for dismissal, Defendants also argue that Plaintiffs' claims should be dismissed because Plaintiffs have failed to allege specific acts or misrepresentations by Defendants that have caused or threaten to cause injury to Plaintiffs. Defendants assert that Plaintiffs have not alleged actual facts from which one might reasonably believe that the products are not in fact equivalent. Defendants further contend that Plaintiffs' failure to plead "specific, actual, and actionable statements" in advertising requires dismissal of the Lanham Act claims.

Plaintiffs respond that they are not alleging any violation of FDA regulations, but are simply asserting claims based on "false and misleading claims of generic equivalence and substitutability" that Defendants have made. Plaintiffs argue that Defendants' representations are false because they have no studies or comparative clinical evidence to support them, AllanDerm is not rated as equivalent in the Orange Book[3], and AllanDerm does not work as well as XenaDerm. Plaintiffs assert that courts have consistently held that false and misleading misrepresentations of generic

---

[2] 21 U.S.C.A. §§ 301-395 (West 2007).

[3]According to the Complaint, "To assist pharmacists and others in making drug product selection decisions, the FDA regularly publishes a list of interchangeable prescription drugs in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as 'The Orange Book.'" Compl. ¶ 22. However, the Orange Book does not list every drug. *Id.* It does not list XenaDerm, and thus cannot list AllanDerm as a generic to XenaDerm. *Id.*

equivalence and substitutability are actionable under the Lanham Act even if the truth of the facts underlying them may be generally within the purview of the FDA, and courts may use the FDA definition of equivalence to determine the falsity of these statements.

III. Analysis

The Court first turns to the issue of whether Plaintiffs have stated a claim with sufficient specificity to survive a 12(b)(6) motion. The Court will then determine whether Plaintiffs' claims are precluded by the FDA's primary jurisdiction to interpret and enforce the FDCA.

A. Failure to state a claim

Defendants contend that, since the Plaintiffs admit that they have no evidence regarding whether AllanDerm is in fact generic or equivalent to XenaDerm, Plaintiffs' claim is speculative. Further, Defendants contend that "the Original Complaint fails to allege any specific action, or omission to act, by Defendants that has caused or threatens to cause injury to Plaintiffs. Instead, a careful reading of the Original Complaint reveals an interweaving of suppositions and innuendo about Defendants with actions that 'could' or 'might' be taken by a nationwide complex of learned and extremely sophisticated intermediary consumers such as medical doctors, pharmacists, nurses, healthcare facilities, and distributors of medicines and medical products." Further, Defendants' motion complains that "Plaintiffs' Original Complaint does not plead one single instance of actual confusion; not even one instance of any person raising a question concerning any aspect of the products at issue" and "does not attach a single exhibit or incorporate a single document supporting its allegations of harm or threatened harm."

In their Reply, Defendants emphasize that Plaintiffs have failed to "plead specific, actual, actionable statements in advertising" to support a Lanham Act claim. Relying on *Mylan Labs. v.*

Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993), Defendants argue that, "in order to state a claim for relief under §43 of the Lanham Act, [a plaintiff is] required to point to some claim or representation that is reasonably clear from the face of the defendants' advertising or packaging inserts." However, Defendants contend, "The Plaintiffs' Complaint does not contain even one allegation of a false or misleading affirmative statement in advertising or marketing by the Defendants." Instead, Defendants argue, "The Plaintiffs' real complaint seems to be that some medical professionals have concluded – without any action at all by the Defendants – that the two products are equivalent, and that the Defendants have not tried to correct this conclusion." Defendants assert that "[t]he Lanham Act forbids false advertising, but does not require that the Defendants correct an allegedly wrong impression that they did not create by some affirmative act. Because the Plaintiffs have not (and cannot) allege any specific, false or misleading statement by the Defendants their claims must be dismissed."[4]

As noted, Plaintiffs assert four claims against Defendants: (1) false advertising under section 43(a) of the Lanham Act; (2) unfair competition under section 43(a) of the Lanham Act; (3) common-law unfair competition (under Texas law); and (4) common-law misappropriation (under Texas law). Section 43(a) of the Lanham Act, codified at 15 U.S.C. § 1125, provides in part:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which--

[4]Relying on a False Claims Act case from the Fifth Circuit, Defendants argue that Rule 9's particularity requirements apply, and that "[t]he time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby must be stated in a complaint." However, the Fifth Circuit has not held that a heightened pleading standard applies to false advertising claims under § 43(a) of the Lanham Act.

> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). Courts have interpreted this section of the Lanham Act as providing "protection against a 'myriad of deceptive commercial practices,' including false advertising or promotion." *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 495 (5th Cir. 2001).

To recover under the Lanham Act for false advertising, a plaintiff must prove the following elements: "(1) a false or misleading statement of fact about a product; (2) a statement which actually deceived or had the capacity to deceive a substantial segment of potential consumers; (3) a material deception in that it was likely to influence a consumer's purchasing decision; (4) the product was in interstate commerce; and (5) plaintiff had been or was likely to have been injured as a result of the statement at issue." *Id.* There are two types of actionable statements for Lanham Act purposes: statements that are literally false and statements that, while not literally false, implicitly convey a false impression or are misleading and likely to deceive consumers. *Id.* If the statement is shown to be misleading, the plaintiff must also produce evidence of the statement's impact on consumers, referred to as "materiality." *Healthpoint, Ltd. v. River's Edge Pharms., L.L.C.*, Civ. A. No. SA-03-CV-984-RF, 2005 WL 356839 (W.D. Tex. Feb. 14, 2005).

Healthpoint also asserts an unfair competition claim under Section 43(a), as well as under

Texas common law.[5] Unfair competition under Texas law "is the umbrella for all statutory and nonstatutory causes of action arising out of business conduct which is contrary to honest practice in industrial or commercial matters." *Taylor Publishing Co. v. Jostens, Inc.*, 216 F.3d 465, 486 (5th Cir. 2000). The category of unfair competition includes a number of types of objectionable trade practices, including trademark infringement, dilution of good will, misappropriation of business value, "palming off," and theft of trade secrets. *Healthpoint, Ltd. v. River's Edge Pharmaceuticals, LLC*, No. SA-03-CV-984-RF, 2005 WL356839 (W.D. Tex. Feb. 14, 2005). The tort requires that the plaintiff show an illegal act by the defendant that interfered with the plaintiff's ability to conduct its business. *Id*. (citing *Taylor Pub.*, 216 F.3d at 486). Although the illegal act need not necessarily violate criminal law, it must at least be an independent tort. *Id.* As in *Healthpoint v. River's Edge*, because Plaintiffs' allegations in support of their unfair competition claim are essentially the same as those in support of their false advertising claim, the Court construes the Complaint as alleging a primary tort of false advertising with a dependent or supplemental claim for unfair competition, and thus the unfair competition claim is dependent upon the false advertising claim. *Id.*; *see also Healthpoint v. Ethex*, Civ. A. No. 01-CV-646-OG, 2004 WL 2359420 (W.D. Tex. July 14, 2004) ("Healthpoint's allegations in support of its claim of common law unfair competition are those also alleged for false advertising in violation of the Lanham Act. Accordingly, the claim for common law unfair competition will be analyzed under the elements of the claim of false advertising in violation

[5]As noted by Plaintiffs, absent an argument that there are differences between the federal and state versions of unfair competition claims, courts in the Fifth Circuit analyze these claims together. *See King v. Ames*, 179 F.3d 370, 374 (5th Cir. 1999).

of the Lanham Act.")[6]

Plaintiffs argue that their claims for false advertising and unfair competition are supported by their allegations that, in their commercial advertising, Defendants have made false and misleading statements of fact concerning AllenDerm and XenaDerm, that the ads have deceived customers that AllanDerm is equivalent to and substitutable for XenaDerm, that the deception is material, having lead drug buyers and pharmacies to substitute AllanDerm for XenaDerm, and that Healthpoint has been injured as a result. As a result, Plaintiffs argue that they have adequately stated a claim for false advertising under the Lanham Act, and dependent claims of unfair competition under the Lanham Act and common law.

Plaintiffs allege that "Allan falsely promotes AllanDerm as a generic substitute to customers including wholesalers, retailers, chains, distributors, mail order houses, independent pharmacies, managed care organizations and/or others." Compl. ¶ 6. Plaintiffs allege that they have "expended enormous resources developing XenaDerm and building brand awareness."*Id.* ¶ 9. Plaintiffs allege that Allan "manufactures, formulates, and distributes what it calls 'generic' or 'brand-equivalent' versions of brand-name prescription drugs." *Id.* ¶ 10. Plaintiffs allege that, in 2006, Allan decided to create a "knock-off" of XenaDerm and contacted Pharma-Pac to manufacture it. *Id.* ¶ 11. "Upon information and belief, Allan began marketing its knock-off ointment product as 'AllanDerm-T Ointment" in 2006." *Id.* ¶ 12.

Further, "[u]pon information and belief, prior to launching AllanDerm, Defendants did not perform any tests to determine if it was bioequivalent or therapeutically equivalent to XenaDerm,

---

[6] Relatedly, Defendants do not directly address the misappropriation claim in their motion to dismiss, other than to assert that it falls with the Lanham Act claim.

nor did Defendants spend the time and resources necessary to ensure that their product would be as pharmaceutically elegant and effective as XenaDerm." *Id.* ¶ 12. "Despite the absence of clinical equivalency testing, Allan nevertheless markets AllanDerm ... as a generic equivalent and substitute for XenaDerm." *Id.* ¶ 13. "Upon information and belief, Allan has had AllanDerm linked to XenaDerm in drug dispensing databases and price systems that represent a major drug marketing communications channel to pharmacists and chain store buyers, and are used by pharmacists to decide which drug product to dispense when filling a prescription." *Id.* Plaintiffs further allege that, in its advertising and promotion to drug databases and pricing systems, "Allan has made no effort to differentiate AllanDerm from XenaDerm other than on the basis of price." *Id.* ¶ 14. "Upon information and belief, in commercial advertising and promoting, Allan states and implies that AllanDerm is a generic version of XenaDerm and labels AllanDerm as a generic equivalent to XenaDerm." *Id.* Further, "AllanDerm does not inform drug databases and pricing systems, wholesalers, distributors, pharmacies or pharmacists that there are no comparative studies showing that its ointment is therapeutically equivalent or bioequivalent to XenaDerm." *Id.* Plaintiffs allege that, "[b]ased upon Defendants' commercial advertising and promotion, drug databases and pricing systems, as well as wholesalers, distributors, formularies, and retail pharmacy chains have 'linked' AllanDerm as a generic equivalent to XenaDerm" and "AllanDerm is now substituted as a generic for XenaDerm in pharmacies." *Id.* ¶ 17. Plaintiffs allege that "[t]his could not occur unless Defendants had successfully created the false impression among drug databases and pricing systems, wholesalers, distributors, formularies, retail pharmacy chains and pharmacists that AllanDerm is genuinely generic to and substitutable for XenaDerm." *Id.*

Plaintiffs further allege that AllanDerm is not a generic to or substitute for XenaDerm. *Id.*

¶ 23. "Upon information and belief, Defendants have not performed or commissioned any studies comparing the effectiveness of their ointment to XenaDerm and have no clinical evidence that AllanDerm is bioequivalent or therapeutically equivalent to XenaDerm." *Id.*[7] "Additionally, upon information and belief, AllanDerm is not bioequivalent or therapeutically equivalent to XenaDerm, and produces inferior clinical results compared to XenaDerm." *Id.*

Plaintiffs allege that they have been harmed because Defendants' marketing efforts have misled consumers into believing that AllanDerm is a generic to XenaDerm, and substitutions of inferior AllanDerm for XenaDerm are eroding XenaDerm sales and goodwill. *Id.* ¶ 25.

Plaintiffs allege that Allan's advertisements and promotional claims about AllanDerm are literally false and/or impliedly false and misleading because AllanDerm is not generic to or substitutable for XenaDerm. *Id.* ¶ 28. Plaintiffs further allege that Allan is liable under section 43(a) because it knows or has reason to know that entities are falsely describing AllanDerm as a generic equivalent to and substitute for XenaDerm, but continues to supply XenaDerm to those entities. *Id.* ¶ 29. Plaintiffs allege that Pharma Pac is liable because it knows or has reason to know of Allan's false or misleading advertising of AllanDerm as a generic equivalent or substitute for XenaDerm, but continues to supply AllanDerm to those entities. *Id.* ¶ 30.

Boiled down to its essence, Plaintiffs' false advertising claim is based on the allegation that Allan falsely advertises and promotes AllanDerm as a generic equivalent and substitute for XenaDerm, but (1) Allan performed no testing to determine if AllanDerm was bioequivalent or

[7] Plaintiffs' Complaint states that, "Generic drugs are *therapeutically equivalent* to their branded rivals. To be *therapeutically equivalent*, the products must be *pharmaceutically equivalent*– e.g., have the same active ingredients, strength, and dosage form – and they must be *bioequivalent*– deliver the active ingredients to the body at the same rate and in the same amount." Compl. ¶ 19 (emphasis in original).

therapeutically equivalent to XenaDerm, (2) Defendants did not spend the time and resources necessary to ensure that their product would be as pharmaceutically elegant and effective as XenaDerm, (3)AllanDerm is not listed as a generic equivalent in the Orange Book, and (4)AllanDerm does not work as well as XenaDerm and is inferior to XenaDerm. The only specific false representation listed in the Complaint is that in paragraph 14: "Upon information and belief, in commercial advertising and promoting, Allan states and implies that AllanDerm is a generic version of XenaDerm and labels AllanDerm as a generic equivalent to XenaDerm." In a footnote to the Complaint, Plaintiffs state that much of the marketing for a generic drug occurs "'under the radar' in targeted communications with drug wholesalers, retailers and others, who are encouraged to 'link' the generic product to the branded drug in their databases." Plaintiffs state that they are not privy to these communications and that "there are many unseen and unheard sales pitches and additional pieces of evidence that will only come to light through discovery."

In *Mylan Labs v. Matkari*, the Fourth Circuit concluded that the plaintiff sufficiently stated a false advertising claim by alleging that the defendant "falsely represented" that its product was "bioequivalent to its innovator counterpart and other approved generic equivalents," that the product was "entitled to an AB rating" from the FDA, or that the product was the "generic alternative" to the innovator drug. *Mylan Labs*, 7 F.3d at 1138. In support of those claims, the plaintiff alleged that FDA approval had been obtained through fraud and ultimately was withdrawn, that the data for the bioequivalence studies had been falsified or was seriously unreliable, and that bioequivalence studies had not been performed or had been performed on a drug that was manufactured differently than the advertised drug. *Id.* In short, the Fourth Circuit held, the plaintiff "set forth in the complaint sufficiently particularized allegations of false or misleading misrepresentations to sustain, for now,

Count 3." *Id.* Nevertheless, the Court concluded that Mylan's claims that the defendants' falsely represented that their drugs had been "properly approved by the FDA" failed. This was not because such a false representation would not be actionable, but because Mylan did not point to any statement or representation in the defendants' advertising that declared such "proper FDA approval." The court rejected Mylan's assertion that the very act of placing a drug on the market, with standard package inserts often used for FDA-approved drugs, somehow falsely implied that the drug had been "properly approved by the FDA" as "too great a stretch under the Lanham Act" that would, "in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the [FDCA]." *Id.* at 1139. Thus, the court held, "[i]n order to state a proper claim for relief under § 43(a) of the Lanham Act, Mylan was required to point to *some* claim or representation that is reasonably clear from the face of the defendants' advertising or package inserts." *Id.*

The Court finds that Plaintiffs have alleged a specific false or misleading misrepresentation in Defendant's commercial advertising–that Allan states and implies that AllanDerm is a generic equivalent of XenaDerm, when in fact it is not. The fact that Plaintiffs do not have the exact advertisement at this early stage of the litigation is not sufficient to warrant dismissal, as the facts alleged in the Complaint are sufficient to bring the allegations beyond the speculative level. Other district court decisions have considered substantially similar allegations and found them sufficient to survive a 12(b)(6) motion to dismiss. *See Axcan ScandiPharm, Inc. v. Ethex Corp.*, 2007 WL 3095367 (D. Minn. 2007) ("Stated differently, Axcan has pleaded the 'who [the Defendants], what [false advertising], where [in ads targeted to drug databases, wholesalers, and pharmacies], when [since the late 1990's], and how [falsely claiming their drugs are generic equivalents or substitutes]' of its claims.") (brackets in original); *Solvay Pharmaceuticals, Inc. v. Global Pharmaceuticals*, 298

F. Supp. 2d 880, 886 (D. Minn. 2004) ("The Complaint asserts that Defendants have made false and misleading representations in advertising and marketing regarding the substitutability of Lipram for Creon. These assertions of false and misleading representations are sufficiently particularized to facilitate Defendants' ability to respond to and prepare a defense to the allegations brought against them.").

For similar reasons, the Court finds that Plaintiffs have adequately stated a claim for unfair competition. Plaintiffs need not attach proof of actual confusion to their Complaint. It is sufficient that they have alleged that the targeted audience was actually misled and that these entities have linked AllanDerm and XenaDerm. *See* Complaint ¶¶ 17, 25.

The Court concludes that Plaintiffs' Complaint sufficiently states a claim to survive a 12(b)(6) motion to dismiss. The Court thus turns to the more difficult issue of whether this Lanham Act claim infringes on the FDA's primary jurisdiction.

B. Preclusion by the FDA's primary jurisdiction to enforce the FDCA

Defendants argue that Plaintiffs' claims must be dismissed because they are precluded by the FDCA and the FDA's primary jurisdiction to enforce the FDCA. The overlap and potential conflict between the Lanham Act and the FDCA is not a new issue. As one court recently explained, "The FDCA and the Lanham Act overlap to the extent that both regulate drug products in the marketplace. Courts have recognized the potential conflict between the two Acts and have struggled to define the proper scope of each law. Courts have come to the general conclusion that the FDA's enforcement of the FDCA is primarily concerned with the safety and efficacy of new drugs, while the Lanham Act is focused on the truth or falsity of advertising claims." *Axcan Scandipharm, Inc. v. Ethex Corp.*, 2007 WL 3095367 (D. Minn. 2007). One may not bring a Lanham Act claim that "requires

direct application or interpretation of the FDCA or FDA regulations." *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 837 (W.D. Tex. 2001). Therefore, Plaintiffs' Lanham Act claims are precluded if direct application or interpretation of the FDCA or FDA regulations is necessary to prove a crucial element of the claim. *Id.* at 838. However, "[t]here is no single, bright-line test to distinguish sustainable from non-sustainable claims." *Id.* at 837.

In *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.* (*Grove Fresh I*), 720 F. Supp. 714 (N.D. Ill. 1989), the plaintiff brought a Lanham Act claim in which it accused the defendant of falsely representing that its orange juice was made from "100% orange juice." In denying the defendants' motion to dismiss, the court stated that the plaintiff was using the FDA regulation defining "orange juice from concentrate" in order to "establish the standard or duty which defendants allegedly failed to meet" and that "[n]othing prohibits Grove Fresh from using the FDCA or its accompanying regulations in that fashion." *Id.* at 716. The court carefully distinguished between a claim based "solely on the FDCA or FDA regulations" and a claim that uses an FDA regulation to establish the standard for finding a Lanham Act violation:

> In the instant case, ... Grove Fresh does not base its claim solely on the FDCA or FDA regulations. Grove Fresh alleges that defendants have violated section 43(a) of the Lanham Act. Even without the FDA regulation defining "orange juice from concentrate," Grove Fresh could attempt to establish a violation of section 43(a). Grove Fresh would simply need to provide other evidence establishing the proper market definition of "orange juice from concentrate." Thus, Grove Fresh has asserted an independent basis for its claim ....

720 F. Supp. at 716.

However, just two months later, the same court (before a different judge) in *Grove Fresh Distributors, Inc. v. Everfresh Juice Co*., 1989 WL 152670 (N.D. Ill. 1989) ("*Grove Fresh II*"), concluded that Grove Fresh could not rely on the FDCA definition of "100% pure orange juice from

concentrate" in proving its Lanham Act claim. *Id.* at *3. Grove Fresh alleged that Everfresh was marketing its product as 100% orange juice from concentrate even though it contained other ingredients, and brought a Lanham Act claim based on defendant's noncompliance with the relevant FDCA definition for labeling a product 100% orange juice from concentrate. The court denied the motion to dismiss, but limited the plaintiff's ability to prove its claims by referencing the FDA regulations:

> Grove Fresh argues that it does not really invoke the FDCA, it relies on the FDCA indirectly, solely (or merely) to establish the standard which defendants failed to meet. Distinctions between direct and indirect must sometimes be made but they are difficult to defend and ought to be avoided. Reliance upon the FDCA to establish a standard which defendant must meet is a very substantial use of the FDCA. Where Congress has precluded private causes of action under the FDCA, we find it difficult to justify the use of the FDCA to establish a crucial element of a private cause of action under the Lanham Act. ... Grove Fresh cannot base its Lanham Act claim upon the violation of the FDCA.
>
> This is not, however, necessarily fatal to the Lanham Act claim. Judge Bua has held, and I agree, that "[e]ven without the FDCA regulation defining 'orange juice from concentrate', Grove Fresh could attempt to establish a violation of section 43(a) ... Grove Fresh would simply need to provide other evidence establishing the proper market definition of 'orange juice from concentrate.' " *Grove Fresh v. Flavor Fresh*, 89 C 1114 (N.D.Ill.1989). This may not be a very promising course for Grove Fresh to undertake. There may, in fact, be no proper market definition of "100% Orange Juice from Concentrate" outside of the FDCA and its regulations, or, if there is, it may be inconsistent with the regulations definition and thus preempted by that definition. Striking all reference to the FDCA regulations leaves a still valid (if hard to prove) complaint. The Motion to Dismiss the first count in each complaint is denied.

In *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1138 (4th Cir. 1993), the court declined to dismiss a Lanham Act claim alleging false statements of bioequivalency. The court explained that the plaintiff could prevail on such a claim by proving that the test results supporting the statement were "'not sufficiently reliable to permit one to conclude with reasonable certainty that they

established' the claim made." In finding the allegations sufficient to survive the motion to dismiss, the court took particular notice of Mylan's accusations that defendant "falsely represented" its product as "bioequivalent" or a "generic alternative," that it deserved an "AB" rating from the FDA, and that studies to prove bioequivalence had either not been performed or had been falsified. However, the court dismissed the plaintiff's claim that the defendant's placing of the product on the market implied FDA approval because the claim lacked the false representation necessary for a Lanham Act claim, and was thus simply a disguised attempt to enforce the FDCA.

In *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817 (W.D. Tex. 2001), the court considered the FDA's primary jurisdiction over several claims, including a claim that Ethex falsely advertised its product as an alternative to plaintiff's product. *Id.* at 824. Specifically, the plaintiff complained that the defendant had made false and misleading statements that its ointment was "a generic form of, the same as, a substitute for, an alternative to, a therapeutic equivalent to or substitute for" plaintiff's ointment. *Id.* at 830. The court concluded that the underlying question of whether Ethezyme is a "generic" to Accuzyme is an issue "committed to the FDA" that the district court should decline to address. *Id.* at 841-42. Healthpoint argued "that Ethex has not demonstrated that Ethezyme is therapeutically or bioequivalent to Accuzyme and, therefore, Ethex should not be allowed to suggest that Ethezyme is freely substitutable, under most state laws, as 'generically' equivalent." *Id.* at 842-43. Ethex argued that to allow Healthpoint to pursue its claim "would require Ethex 'to prove bioequivalence to Accuzyme, ... [and] ... in effect, Ethex would be required to submit an ANDA [Abbreviated New Drug Application] to the FDA for Ethezyme when there is no procedure that would allow for such filing.'" The court stated that, "[i]t seems clear that in addressing claims of 'equivalent to' or 'alternative to,' the Court should not change the FDA's

definitions of such related terms of art as 'pharmaceutical equivalent,' 'therapeutic equivalents,' 'bioequivalence,' and 'pharmaceutical alternative.'" *Id.* at 843. "New definitions of FDA terms would undercut national uniformity regarding federal laws regulating the drug market or would confuse the public and undermine confidence in the drug supply in general and generic drugs in specific." *Id.* Thus,

> Although Lanham Act or related common law claims that concern whether Ethezyme is "the same as" Accuzyme–to the extent that determination requires a simple comparison of ingredients and does not entail a decision on whether sodium metabisulfite should be listed as an active ingredient–appear to be properly before the District Court, a determination of whether Ethezyme is "equivalent" to Accuzyme appears to be inextricably linked to the determination of whether Ethezyme is being marketed lawfully, a matter within the exclusive enforcement domain and "particular expertise" of the FDA. Similarly, the "task of identifying in the first instance whether one drug is the generic equivalent of another" belongs to the FDA . . . The term "alternative" is less problematic . . . [it] does not imply identity or equivalence.

Id. at 843-44. Based on this reasoning, the court declined to consider the issue of whether Ethezyme was in fact a "generic" or "equivalent" product to Accuzyme, but held that claims based on allegedly false statements that the products were the "same" or that one was a "high quality alternative" were properly before the court. *Id.* at 846 nn.140-41. The court recognized that Ethex's witnesses testified that there are "generic alternatives" that do not need to be approved by the FDA and that the term "generic" may be used "without confusion with respect to drugs that are similar but not necessarily therapeutically equivalent," but noted that it is in the FDA's interest to ensure that "only one definition of FDA terms of art, such as 'therapeutically equivalent' and 'generic,' is used in the context of drug approval, acceptance and use." *Id.* at 866 (citations omitted). The Court ultimately enjoined Ethex from including in further print advertisements comparing Ethezyme to Accuzyme language that "neither brand nor generic papain-urea compounds are subject to FDA approval or

rating," because, in the context of other representations, it was misleading and inconsistent with its claim that Ethezyme is a "generic" equivalent. *Id.* at 866. "The over-all effect [was] to create the misleading impression that Accuzyme is the 'brand' and Ethezyme is a 'generic substitute for Accuzyme, when it has not been determined that Ethezyme is a 'generic' alternative to Accuzyme." *Id.* at 867.[8]

Healthpoint v. Stratus Pharmaceuticals, 283 F. Supp. 2d 769, 792 (W.D. Tex. 2001), presented claims based on false representations that defendant's products were "generic" to plaintiff's and could be substituted for prescriptions of plaintiff's products. Though noting that the question whether two products are generic is best left to the FDA, the court concluded that "a drug manufacturer making a claim that a non-approved drug is 'generic' to or a 'generic equivalent' of another non-approved drug must use the FDA's definition of 'generic' and, when such a

---

[8] In a later order by Judge Garcia concerning Magistrate Judge Mathy's recommendation on the preliminary injunction and a motion to stay, the court stated,

> Ethex Corporation further objects to the Magistrate Judge's recommendation that the Court should abstain from hearing the issue of whether Ethezyme is, in fact, "generic" or "equivalent" to Accuzyme, but that it may consider whether representations that Ethezyme is "generic" or "equivalent" to Accuzyme without sufficient substantiation (i.e. supporting test data) are false or misleading. Ethex contends that these two issues are not distinguishable. (Dkt.# 225, pp. 19-20). On the other hand, Healthpoint contends the issues are distinguishable because the first issue (whether Ethezyme is, in fact, "generic or equivalent to" Accuzyme) is a regulatory question to the extent such terms must be interpreted or defined by the FDA, whereas the second issue is a marketing question (whether it is appropriate for Ethex to market Ethezyme as a generic or equivalent drug without test data to support such representation). (Dkt. # 245, pp. 10-11). Although the Court agrees that the distinction between such issues may be blurry at times, the Magistrate Judge analyzed these issues thoroughly, and the Court does not believe the facts or law compel a different conclusion.

Healthpoint v. Ethex, Civ. A. No. 00-757-OG, 2001 WL 34897840 (W.D. Tex. Aug. 3, 2001).

representation is challenged, as here, through a Lanham Act false advertising claim with specific allegations that the use of the terms is false and unsubstantiated, must defend and be prepared to demonstrate why it stated that its drug is a 'generic equivalent,' that is, is 'identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.'" *Id.* at 792. The court explained:

> The primary jurisdiction of the FDA would not appear to bar a court from deciding Healthpoint's false advertising claim that Stratus has made false claims of "generic equivalence" or "bioequivalence" and has allegedly falsely represented that Kovia and Ziox have the "same ingredients" or the "same active ingredients." There is a distinction, on the one hand, between respecting the FDA's primary jurisdiction to determine in the first instance whether a drug is lawfully marketed, "generic," "bioequivalent," "therapeutically equivalent," "pharmaceutically equivalent" and, on the other hand, a Lanham Act claim that a false statement has been made about a product. Even though the FDA has not required Stratus to demonstrate the equivalence of Kovia to Accuzyme or the equivalence of Ziox to Panafil White, Stratus is not free to make false or misleading statements about its product. To hold to the contrary would mean that an administrative scheme could eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction. For example, if Stratus represents that its two ointments are "bioequivalent," "generically equivalent," "equivalent" or have "the same active ingredients" or "the same ingredients" or "the same active ingredients in the same amounts," consumers and competitors have a right to expect that such representations have factual support and the Lanham Act provides a vehicle to enforce that expectation.

Id. at 792-93 (footnotes omitted). The court stressed that Healthpoint was not alleging that Stratus had falsely implied FDA approval, but instead the claims were "of false or misleading comparisons between two specific products in the context of comparative advertising and promotion relating to whether one drug can be substituted for another under state law." *Id.* at 793.

Later in the litigation, the court considered motions for summary judgment. The court considered whether Stratus's use of the term "generic" was false, "[s]etting aside the questions of whether under the FDA standards, Kovia and Ziox are generics for Accuzyme and Panafil, questions

for the FDA and not for the Court." *Healthpoint v. Stratus Pharmaceuticals, Inc.*, 273 F. Supp. 2d 871, 891 (W.D. Tex. 2001). The court noted that the record reflected that defendant had attempted to market its product in such a way as to suggest that the products were interchangeable, but "[w]hen and what Stratus knew of the differences in the products and whether even with the knowledge Stratus continued to market Kovia as a generic for Accuzyme are questions of fact." *Id.*

In *Ethex Corporation v. First Horizon Pharmaceutical Corporation*, 228 F. Supp. 2d 1048 (E.D. Mo. 2002), First Horizon claimed that Ethex illegally sought to have its products listed as generic versions of First Horizon's product in pharmaceutical drug databases. *Id.* at 1051. Neither party's products (prenatal vitamins) were subject to FDA approval. *Id.* at 1052. First Horizon argued that calling the vitamins generic "is an implicit representation that the vitamins have met the test of bioequivalency and therapeutic equivalency." *Id.* at 1053. The court discussed the Third Circuit's decision in *Sandoz Pharmaceuticals Corp. v. Richarson-Vicks, Inc.*,[9] stating that it stands "for the proposition that a court should not find a label to be literally false if the complaining party has made no showing other than a proffered interpretation of an agency's regulations" and "cautions courts not to determine preemptively how an administrative agency will interpret and enforce its own regulations." *Id.* The court also discussed *Grove Fresh I*, noting that the court allowed the plaintiff to go forward with its Lanham Act claim because the plaintiff was using the FDA regulation merely to establish the standard or duty, and that, because the plaintiff could have stated a Lanham Act claim without the FDA definition by simply providing other evidence establishing the market definition of the term, the plaintiff was not relying solely on the FDA regulation to pursue its false advertising claim. *Id.* at 1054. The court then concluded that, based on the precedents and the specifics of the

[9]902 F.2d 222 (3d Cir. 1990).

defendants' counterclaim, the claim was precluded:

> While Defendant insists that it is not attempting to privately enforce the provisions of the FDCA, the express language of its own counterclaim speaks to the contrary. The touchstone of Defendant's argument focuses on the fact that the word "generic" implies FDA endorsement and certain FDA-defined concepts. *See* Defendant's Answer and Counterclaims ¶ 43 (unless a drug has an approved ANDA, it cannot be properly and correctly represented to be generic to another drug), ¶ 57 (the term generic as used in the pharmaceutical industry presupposes FDA approval), ¶ 63 (marketing vitamins as generic infers equivalence and interchangeability). Defendant argues that pharmacists, upon seeing Plaintiffs' vitamins marketed as generic, were confused into believing that they could lawfully substitute Plaintiffs' version of the drug. But the pharmacists could only be confused if "generic" is taken as an implicit representation that the product meets FDA standards of bioequivalence and therapeutic equivalence. The decisions in this area have refused to allow plaintiffs to state a claim based on implicit representations of FDA approval; this Court thinks it inappropriate, then, to sustain a Lanham Act claim based on a representation which somehow implied FDA definitions.
>
> The FDA has not required either parties' drugs to obtain FDA approval. Thus, neither party has tested, nor were they required to test their drugs for bioequivalence and therapeutic equivalence. A pharmacist should know this if he looked in the Orange Book. Moreover, no federal statute or FDA regulation has defined the term "generic." Unlike in *Grove Fresh*, where the term at issue was clearly defined in an FDA regulation, this Court would be forced to determine FDA policy in order to determine the truth or falsity of the "generic" nomenclature. This Court agrees with the majority of courts that have handled this issue that this type of claim is better left to the FDA who has the expertise in enforcing and interpreting its own complicated regulations. This is especially true in this case where the FDA has not even required prenatal vitamins to meet any standards.
>
> For these reasons, to the extent Defendant claims a violation of the Lanham Act based on Plaintiffs' marketing their vitamins as generic, or alternatives to Defendant's product, or inducing illegal substitution, that portion of the Counterclaim is dismissed.

Id. at 1055.

In *Solvay Pharmaceuticals, Inc. v. Global Pharmaceuticals ("Solvay I")*, 298 F. Supp. 2d 880 (D. Minn. 2004), Solvay alleged that defendant was falsely marketing Lipram as a substitute for its pancreatic enzyme supplement Creon. Solvay alleged that defendants were "marketing their

Lipram products either expressly or by implication as 'generic' versions of Creon, even though Lipram is not, in fact, equivalent to Creon." *Id.* at 882. Neither Creon nor Lipram appeared in the Orange Book, and neither was subject to FDA approval. Solvay alleged that the defendants had not studied whether Lipram is a therapeutic equivalent of Creon and that it was not pharmaceutically equivalent to Creon. *Id.* Defendants moved to dismiss the suit as precluded by the FDCA. The court found *Mylan* to be instructive, noting that the *Mylan* court "would not sustain claims for false representations of FDA approval, but did allow claims related to allegedly false statements regarding bioequivalence or generic equivalence." *Id.* at 884. The court then concluded that Solvay's claims "are not related to FDA approval, or lack thereof," but were claims "based upon Defendants' allegedly false marketing assertions that the Lipram supplements are 'generic,' 'comparable,' 'substitutable' or 'equivalent' to Solvay's Creon line." *Id.* Because neither Lipram nor Creon were listed in the Orange Book, "FDA approval is not required in order to substitute the products or to make a determination of bioequivalence or therapeutic equivalence" and "the FDA [did] not regulate the substitution of Lipram for Creon in any manner." *Id.* Thus, "[w]ithout any claims or factual assertions that tie Solvay's claims to FDA approval, Solvay has not attempted to privately enforce the provisions of the FDCA." *Id.* at 885. The Court distinguished *Ethex v. First Horizon*, noting that the "*Ethex* court focused on the express language of the counterclaims, noting that '[t]he touchstone of Defendant's argument focuses on the fact that the word 'generic' implies FDA endorsement and certain FDA-defined concepts." *Id*. In contrast, "Solvay's claims [did] not relate to or allege false assertions of FDA approval" and thus "the Court does not run the risks expressed in *Ethex* of usurping the FDA's approval or encroaching upon FDA jurisdiction when no FDA regulatory approval over the substitution is either alleged or in effect." *Id.*

In *Solvay Pharmaceuticals, Inc. v. Ethex Corp. ("Solvay II")*, Civ. A. No. 03-2836, 2004 WL 742033 (D. Minn. 2004),[10] the court declined to dismiss false advertising claims based on the allegation that Ethex had marketed its "products either expressly or by implication as 'equivalent,' 'comparable,' and 'generic' versions of Creon." Ethex argued that whether the drugs were in fact equivalent was an issue to be determined by the FDA and not in a private action. Solvay, on the other hand, had "disclaimed any FDA related allegation." Relying on *Grove Fresh I*, the court explained that Solvay was permitted to use FDA regulations' definitions of "bioequivalence, pharmaceutical equivalence, and therapeutic equivalence" to establish the standard by which allegations of literal falsity are to be evaluated. The court opined that "'false statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA,' where the truth or falsity of the statements in question can be resolved through reference to standards other than those of the FDA." The court cited *Mylan Labs v. Matkari* as support, noting that "[w]hether the tests cited by Matkari were falsified, unreliable, or non-existent and thus insufficient to support a claim of 'bioequivalence' was a factual issue properly considered by the court." The court distinguished *Ethex v. First Horizon* because Solvay was "not relying on either explicit or implicit FDA endorsement or terms that only the FDA can define." Instead, "[s]imilar to the plaintiff in *Grove Fresh*, Solvay may use the FDA regulations listing definitions of bioequivalence, pharmaceutical equivalence, and therapeutic equivalence to establish the appropriate standard by which to judge the literal falsity of Ethex's advertisements." The court also cited to *Grove Fresh*'s statement that the plaintiff could attempt to establish a violation of section 43(a) by

[10] *Solvay I* and *Solvay II* involved similar allegations, but were brought against two different defendants. Both cases were brought in the District of Minnesota, but were decided by two different Judges in the District.

providing other evidence of the proper market definition of generic, equivalent, comparable, or substitutable, and stated, "As Ethex acknowledges, and FDA determination is not necessarily required in order for two drugs to be properly considered equivalent." The court thus denied the 12(b)(6) motion because the claim did "not require the Court to determine anything within the particular jurisdiction of the FDA."

In *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967 (E.D. Wis. 2005), the court considered cross-motions for summary judgment in a case involving a prescription drug used for gastrointestinal and urological disorders, Nulev, and a "knock-off' competitor, Neosol. Plaintiffs alleged that, in commercial advertising, the defendant described Neosol and described Nulev as the "reference" product. *Id.* at 971. In considering whether the Lanham Act claim was precluded, the court noted that "the mere FDA regulation of a term dos not necessarily bar all Lanham Act claims that pertain to that term." *Id.* at 974. The court noted that the defendant "has failed to identify any section of the FDCA or its accompanying regulations that the court would be required to interpret or apply." *Id.* at 975. Neither Nulev or Neosol were listed in the Orange Book and there was "no record of the FDA evaluating the two products for pharmaceutical equivalence." Thus, "[i]n the absence of any FDA ruling or ongoing investigation, there is little chance that the court will usurp the role of the FDA." *Id.* The court noted that the defendant conceded that the claims did not run afoul of the FDA's jurisdiction "if Schwarz limits itself to the truth or falsity of the statements made in advertising" and "[t]o hold to the contrary would mean that an administrative scheme could eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction." *Id.* Thus, the court allowed Schwarz "to proceed on all remaining claims to the extent that it is not seeking the interpretation or direct application of any FDA regulation." *Id.* (citing

Grove Fresh I).

In *Pediamed Pharmaceuticals, Inc. v. Breckenridge Pharmaceutical, Inc.*, 419 F. Supp. 2d 715 (D. Md. 2006), plaintiff complained that defendant marketed its product, V-Tann by noting, "Compare the active ingredients in Viravan-S," which was plaintiff's product. Plaintiff asserted that V-Tann had more phenylephrine tannate and pyrilamine tannate than Viravan and the two products had different specification ranges, and thus the products were not pharmaceutically equivalent. Plaintiff also complained that defendant did not perform any tests to determine bioequivalence before launching V-Tann. The court surveyed the applicable case law:

> ... *Mylan* involved drugs for which the FDA had made a determination of equivalency, and thus the FDA's jurisdiction was clear. This case involves a class of drugs that is not required to file a new drug application or an ANDA, and the FDA typically does not make a equivalency determination for these drugs. Other courts have considered preclusion challenges in claims involving non-Orange Book drugs (i.e. where the FDA does not determine equivalency), and have drawn a line between claims that involve application and interpretation of the FDCA and its implementing regulations, and claims that do not. *See Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc*., 388 F.Supp.2d 967, 975 (E.D.Wis.2005) (allowing the plaintiff's complaint to proceed "to the extent that it is not seeking the interpretation or direct application of any FDA regulation"); *Solvay Pharms., Inc. v. Global Pharms*., 298 F.Supp.2d 880, 884 (D.Minn.2004) (allowing the plaintiff's claims to proceed and noting that "FDA approval is not required in order to substitute the products or to make a determination of bioequivalence or therapeutic equivalence"); *Ethex Corp. v. First Horizon Pharm. Corp*., 228 F.Supp.2d 1048, 1055 (E.D.Mo.2002) (allowing the plaintiff's claims to proceed to the extent that the claims did not rely on the FDCA); *Stratus*, 273 F.Supp.2d at 793 (stating that "issues that require direct application or interpretation of the FDCA or its implementing regulations or FDA policies should not be addressed by the Court" but "other issues are able to be resolved without the direct application or interpretation of the FDCA, implementing regulations or FDA policies"); *Healthpoint, Ltd. v. Ethex Corp*., 273 F.Supp.2d 817, 845 (W.D.Tex.2001) ("There is a distinction between respecting the FDA's primary jurisdiction to determine in the first instance whether a drug is lawful, 'generic,' 'bioequivalent,' 'therapeutically equivalent,' or 'pharmaceutically equivalent' and, on the other hand, a Lanham Act claim that a false statement has been made about a product.").

> When the advertising at issue directly or indirectly implied that one non-Orange Book drug was the generic of or equivalent to another drug, courts have split over whether a claim was precluded. *See First Horizon*, 228 F.Supp.2d at 1055 (stating that this issue "is better left to the FDA" because "this Court would be forced to determine FDA policy in order to determine the truth or falsity of the 'generic' nomenclature"); *Ethex*, 273 F.Supp.2d at 846 n.140 (finding the generic claim was within the FDA's jurisdiction); *Stratus*, 273 F.Supp.2d at 793 n. 147 (same); *but see Schwarz*, 388 F.Supp.2d at 975 (allowing the plaintiff's claim to proceed where the defendant used the term "reference" in comparing its drug to the plaintiff's drug); *Solvay*, 298 F.Supp.2d at 885 (allowing "generic" claims to proceed).

Id. at 724-25 (footnote omitted). The court then agreed "with the analysis in *Schwarz* and *Solvay*, which found that express or implied claims of generic or pharmaceutical equivalence were not precluded where the drug was not listed in the Orange Book and there was no indication that FDA approval is needed to make a claim of equivalency." *Id.* at 725. It continued,

> In the present case, both Viravan and V-Tann appear to be in the class of drugs that is not required to file a new drug application or an ANDA and as a result, neither drug is listed in the Orange Book. There is no evidence that the FDA has made a determination as to whether V-Tann is a generic or therapeutic equivalent to Viravan, or that it is planning to do so. Defendants do not argue that the FDA typically makes an equivalency determination of the class of drugs not listed in the Orange Book. Moreover, Defendants have not pointed specifically to any portion of the FDCA or to any implementing regulations to support their assertion that Plaintiff's claims are based on the FDCA or its regulations, and therefore are precluded.

Id. at 726.

In *Midlothian Laboratories, L.L.C. v. Pamlab, L.L.C.*, 509 F. Supp. 2d 1065 (M.D. Ala. 2007), the court concluded that "[c]ourts have held that a false-advertising claim based on a representation of product equivalency–marketing a product as a 'generic' version of a branded product–may be maintained when 'the truth or falsity of the statements in question can be resolved through reference to standards other than those of the FDA,' but not 'where a claim requires interpretation of a matter that is exclusively within the jurisdiction and expertise of the FDA and

FDCA." *Id.* at 1085 (citing *Solvay*, 2004 WL 742033 at *3). The court noted that, in *Solvay*, the court denied a motion to dismiss, "finding that the plaintiff could prove under the Lanham Act that the defendant's drug product was not substitutable, and that any advertising of the defendant's drug as 'generic' could therefore be proven literally false." *Id.* at 1086. The court noted that the plaintiff supported its claim by asserting that defendant's product was not listed as therapeutically equivalent in the Orange Book, but that this was irrelevant because the products were undisputably not subject to the FDA-regulated drug-approval processes, and thus "any false-equivalency claim based on the fact that Midlothian's product does not appear in the Orange Book is preempted by the FDA's exclusive authority to approve products pursuant to the FDA." *Id.* "The simple fact that [defendant's] product does not appear in the Orange Book cannot support a valid claim of false equivalency under the Lanham Act." *Id.* The court then noted that the plaintiff asserted that the defendant's "representation of generic equivalence, in the absence of therapeutic equivalence testing, is literally false, and misleads pharmacists into believing that [defendant's] product is therapeutically equivalent to [plaintiff's]." *Id.* However, the court stated, this "begs the question of whether therapeutic equivalence, as defined by the FDCA, is the standard by which legitimate generic substitution of medical food products must be judged." *Id.* The court then stated, "This articulation of the claim makes reference to standards of generic equivalence that only the FDA can define, but it does not require interpretation of those standards." *Id.* at 1086-87. "A plaintiff 'may use the FDA regulations listing definitions of bioequivalence, pharmaceutical equivalence, and therapeutic equivalence to establish the appropriate standard by which to judge the literal falsity of [defendant's] advertisements." *Id.* at 1087 (quoting *Solvay*, 2004 WL 742033 at *4). Thus, the court concluded, the plaintiff's "claim that [defendant's] assertion of 'generic equivalence' is false advertising is not

preempted by the FDA to the extent that [plaintiff] seeks to prove its claim with evidence that pharmacists understand 'generic equivalence' to imply therapeutic equivalence (or some other standard of equivalence), rather than with evidence that FDA regulations require therapeutic equivalence (a matter that only the FDA can decide)." *Id.* at 1087.

In *Axcan Scandipharm, Inc. v. Ethex Corporation*, No. 07-2556, 2007 WL 3095367 (D. Minn. Oct. 19, 2007), the court considered Ethex's argument that "by challenging their marketing of Pangestyme and Lipram as 'generic equivalents to' or 'substitutes for' Ultrase, Axcan has necessarily asserted that the Defendants are improperly representing their drugs as 'equivalent' to Ultrase *in the FDA's sense of that term*- in other words, the Defendants understand Axcan's claims to mean that the Defendants are improperly suggesting that Pangestyme and Lipram are pharmaceutically equivalent and bioequivalent to Ultrase" and that "whether their drugs are 'equivalent' to Ultrase in such fashions can only be determined by the FDA." The Court concluded, however, that the defendants "misapprehend the nature of Axcan's claims." It stated that "Axcan does not allege that the Defendants have falsely implied that their drugs are 'equivalent' in the FDA-sense- that is, bioequivalent and pharmaceutically equivalent to Ultrase. Rather, Axcan asserts that, by advertising their drugs as 'generic equivalents to' or 'substitutes for' Ultrase, the Defendants have engaged in false advertising based on 'the proper market definition[s]' of these terms." "Stated differently, Axcan seeks to proffer evidence of the *generally understood meanings* of the terms 'generic equivalence' and 'substitute,' and not the FDA's definition of 'equivalence,' in order to establish the falsity of the Defendants' advertisements. Such claims in no way infringe on the FDA's right to determine whether two drugs are 'equivalent.'" The court further stated, however, that "[t]his is not to say that Axcan cannot use the FDA's definitions of bioequivalence or pharmaceutical

equivalence when seeking to prove its claims. The FDA's 'primary jurisdiction' does not prohibit a plaintiff from relying on the FDA's definitions 'merely to establish the standard [that the] defendants allegedly failed to meet." The Court reasoned that "the issue here is not whether the FDA should deem the Defendants' products to be 'generic' versions of Ultrase; rather, the issue is whether, by advertising and marketing those products as 'generic equivalents to' or 'substitutes for' Ultrase when they do not contain the same ingredients, the Defendants' advertising is literally or implicitly false, based on common understood meanings of 'equivalent' and 'substitute.'" Further, plaintiffs' claims could be maintained "without infringing on the FDA's right to determine whether the Defendant's drugs are 'generic' versions of Ultrase under its own definition of 'equivalence.'"

Defendant Allan argues that Plaintiffs' claims are within the exclusive jurisdiction of the FDA because the claims are "for a violation of the Food Drug & Cosmetic Act." Defendants argue that "[t]here is no doubt that [plaintiffs'] allegations require that the Court infringe on the FDA's exclusive jurisdiction to determine whether AllanDerm-T is in fact a generic equivalent of Xenaderm" and "[a]ll of the Plaintiffs' specific complaints about false impressions or misleading advertising rest on the notion that AllanDerm-T may not satisfy the FDA's definition of a generic or equivalent drug." Defendants further contend that "to prove their case, [Plaintiffs] will have to conduct [bioequivalence and therapeutic equivalence] tests and then ask this Court to assume the precise role of the FDA in determining what the tests prove." In other words, Defendants contend, Plaintiffs can only win if the products are not equivalent, and only the FDA can make that determination. With regard to the common-law claims, Defendants argue that "[t]he only agency with authority to perform the tests and make the determination of generic equivalence is the FDA" and "[b]ecause a 'crucial element' of the claim requires application of the FDCA, it must be

dismissed."

In response, Healthpoint asserts that it "does not allege that Defendants have violated any provision of the FDCA" and that "Defendants would be liable for false advertising even if there were no FDCA governing the pharmaceutical industry." Instead, Plaintiffs argue, "this case is based on the false and misleading claims of generic equivalence and substitutability Defendants have made when advertising Allan Derm" and courts "have routinely held that such claims are actionable under the Lanham Act" "even if the truth of those facts underlying them 'may be generally within the purview of the FDA.'" Thus, Plaintiffs argue, "courts are free to determine the truth or falsity of [defendants'] advertising and may rely on FDA definitions of equivalence to do so." Further, Plaintiffs contend that "Defendants are not free to state or imply that AllanDerm is equivalent to or substitutable for XenaDerm without proper factual support, or to make other false or misleading statements simply because a federal agency regulates drugs. To hold otherwise would mean that an administrative scheme could eviscerate a Lanham Act or related common claim over which the FDA has no jurisdiction."

There is no indication from the Complaint that the FDA has or intends to determine whether AllanDerm is a "generic" to or "substitute" for XenaDerm, or even whether they are pharmaceutically equivalent, therapeutically equivalent, or bioequivalent. Plaintiffs do not claim that Defendants have violated an FDA regulation or FDCA provision. As is evident from the discussion of the applicable precedents, the majority of courts considering this issue in such a context have permitted the Lanham Act claim to proceed. *See Axcan*, *Midlothian*, *Pediamed*, *Schwarz Pharma*, *Solvay I*, *Solvay II*, *Sratus*, *Ethex*. The Court agrees with these decisions, and concludes that Plaintiffs' Lanham Act claims and other dependent claims should be allowed to proceed at this time.

Even among those courts allowing the claims to proceed, however, there is disagreement over whether Plaintiffs can or must use the FDA's definitions of related terms as the applicable standard in evaluating the truth or falsity of the advertising. *Compare Axcan Scandipharm*, 2007 WL 3095367 (plaintiff's claim could proceed if it used the "proper market definition" or "generally understood meaning") *with Solvay II*, 2004 WL 742033 (claim could proceed using FDA regulations or other market definition) *and with Stratus*, 283 F. Supp. 2d 769 (plaintiff must use the FDA's definitions). In this case, it is not clear whether Plaintiffs seek to utilize the FDA regulations to establish the standard or whether they seek to utilize a market definition or definitions under Texas law.[11] Even were they to utilize solely the FDA regulations, it is not clear that this court would have to interpret these regulations in determining the merits of Plaintiffs' claims. Thus, the Court again finds that dismissal is not warranted at this time.[12]

C. Joint Motion for Status Conference and to Amend the Scheduling Order

The parties have moved for a joint status conference, noting that this motion and others are pending before the Court. The Court will grant the motion and will issue an order setting a status conference by separate order. At the status conference, the Court will consider the parties' positions regarding amending the scheduling order, including the trial date, as well as Defendants' Motion for Leave to File Amended Answer and Counterclaim (docket no. 33) and Plaintiffs' Response in Opposition (docket no. 37).

---

[11] *See* TEX. OCCUPATIONS CODE § 562.001 (defining generically equivalent, therapeutically equivalent, and pharmaceutically equivalent).

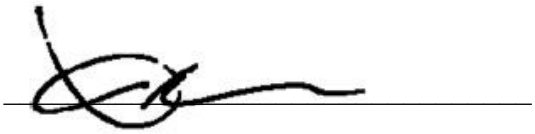
[12] The Court notes, however, that the precedents appear to draw some fine distinctions between allowable and non-allowable claims, and the Court agrees with Judge Garcia that the distinction may be "blurry at times." The Court believes that it would therefore be appropriate to revisit this issue once the contours of Plaintiffs' claims are more developed.

Conclusion

For the reasons stated above, the Court DENIES Defendant's Motion to Dismiss (Docket No. 11) and GRANTS the parties' Joint Motion for a Status Conference (docket no. 44). The Court will issue a separate order setting the status conference.

It is so ORDERED.

SIGNED this 18th day of March, 2008.



XAVIER RODRIGUEZ
UNITED STATES DISTRICT JUDGE